REMARKS

Claims 8 and 32 have been amended. Claims 9 and 33 have been canceled without prejudice. Claims 8, 10-16, 32, 34-41, 46, and 49-51 are now pending for the Examiner's consideration.

By this amendment claims 8 and 32 have been amended to include the limitations previously recited in claims 9 and 33, respectively. No new matter is added.

Applicants request reconsideration of the pending claims in light of the preceding amendments and following remarks.

35 U.S.C. §112, 1st paragraph

Claims 32-41 were rejected under 35 U.S.C. §112, 1st paragraph, for the reasons set forth on pages 2-5 of the Office Action. Claim 32 has been amended to recite methods of treating specific types of cancer—those that are VEGF-, PDGF- or c-Kit-related cancers. Applicants believe the rejection does not apply to the claims as now presented and respectfully request that it be reconsidered and withdrawn.

35 U.S.C. §102 (b)

Claims 8-16, 32-41 and 46 were rejected under 35 U.S.C. §102(b) as being anticipated by Kania et al. (WO 2001/02369, now US Patent No. 6,531,491), for the reasons set forth on pages 5-6 of the Office Action. Applicants respectfully traverse.

With regard to claims 8-16, independent claim 8 as amended recites a dosage form comprising an amount of 0.5 to 30 mg of the compound of formula 1. Kania discloses a generic range of 0.001 to 50 mg/kg, corresponding to 0.07 to 3500 mg for a 70 kg mammal. This disclosed range spans more than four orders of magnitude, and is approximately 10 times less at the lower end, and 100 times greater at the upper end, than the claimed range of 0.5 to 30 mg. It is well-established that disclosure of a broad numerical range does not anticipate a later, more narrow range falling within the broader range; see MPEP 2131.03, citing Atofina v. Great Lakes Chem. Corp, 441 F.3d 991 (Fed. Cir. 2006), wherein a prior art range of 100-500 °C did not describe a claimed range of 330-450 °C with sufficient specificity to be anticipatory. Clearly the broad disclosure of Kania does not anticipate the narrow range now specifically claimed.

Applicants respectfully request that the rejection of claims 8-16 over Kania be withdrawn.

With regard to claims 32-41 and 46, claim 32 has been amended to recite that the cancer is a VEGF-, PDGF- or c-Kit-related cancer, and the amount is from 0.5 to 30 mg. Kania does not

disclose this dosage range, and thus clearly does not anticipate claims 32-41 and 46 as discussed above.

Applicants respectfully request that the rejection of claims 32-41 and 46 over Kania be withdrawn.

35 U.S.C. § 103

Claims 32-41 and 46 were rejected under 35 U.S.C. §103(a) as being unpatentable over Kania et al. (WO 2001/02369, now US Patent No. 6,531,491), for the reasons set forth on pages 6-7 of the Office Action. Applicants respectfully traverse.

Kania discloses a broad range of 0.001 to 50 mg/kg, which would correspond to a range of 0.07 to 3500 mg for a 70 kg mammal, as a generic disclosure of the range of therapeutically effective amounts. There is no teaching or suggestion in Kania to select the narrow range of 0.5 to 30 mg as presently claimed. As noted in MPEP 2144.05, disclosure of a very broad range is analogous to disclosure of a broad chemical genus, and it is well-established that a broad genus encompassing a large number of species does not necessarily render those species obvious. However, even if the disclosure of the range of 0.001 to 50 mg/kg of any of a genus of compounds were considered to render obvious the claimed methods of treatment using a single specific compound and a narrow range of 0.5 to 30 mg, Applicants have submitted ample evidence to rebut any finding of obviousness. In particular, "Applicants can rebut a prima facie case of obviousness based on overlapping ranges by showing the criticality of the claimed range" (MPEP 2144.05). The present specification as well as the references submitted in Exhibit 2 of Applicants' January 24, 2007 response clearly demonstrate that amounts greater than the claimed range present unwanted toxicities and amounts less than the claimed range are not effective in slowing tumor growth. Applicants submit that this showing of criticality effectively rebuts any inference of obviousness over the cited art.

Accordingly, Applicants respectfully request that the rejection under §103(a) be withdrawn.

Double Patenting

Claims 8-16, 32-41, 46 and 49-51 were rejected under the judicially-created doctrine of obviousness-type double patenting over claims 1-11 of U.S. Patent No. 7,141,581, for the reasons set forth on pages 8-9 of the Office Action. Applicants respectfully traverse.

The claims of the '581 patent are directed to methods of treatment with various compounds and without any specific dosing ranges. Nothing in the claims of the '581 patent teaches or suggests any dosing range, much less a range of 0.5 to 30 mg, nor using the specific range of 0.5 to 30 mg of the presently recited single compound. For the same reasons as

discussed above, claims 8-16, 32-41 and 46 are not rendered obvious by the '581 claims. Moreover, claims 49-51 further recite a still narrower dosing range, specific types of cancer, and a dosing frequency of twice per day, and in combination with a specifically selected additional anti-cancer agent (docetaxel and gemcitabine, in claims 50 and 51, respectively). Nothing in the '581 teaches these claimed methods with sufficient specificity to render the claims obvious.

Applicants respectfully request that the double-patenting rejection be reconsidered and withdrawn.

Conclusion

Applicants believe all pending claims are now in condition for allowance. Should there be any issues that have not been addressed to the satisfaction of the Examiner, Applicants invite the Examiner to contact the undersigned attorney.

If any fees other than those submitted herewith are due in connection with this response, including the fee for any required extension of time (for which Applicants hereby petition), please charge such fees to Deposit Account No. 16-1445.

Respectfully submitted,

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